



DEPARTMENT OF VETERANS AFFAIRS

8320-01

Request for Information: Establish a Public-Private Collaboration, "Drug Development Initiative" (DDI), for New Pharmacological Treatments for Post-traumatic Stress Disorder (PTSD)

AGENCY: Office of Research and Development (ORD).

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA) ORD publishes this Request for Information (RFI) to solicit interest in forming public-private collaborations to develop new pharmacological treatments for PTSD. ORD is interested in developing collaborations with organizations that are interested in pursuing clinical trials specifically focused on PTSD. Such research would be detailed through a Cooperative Research and Development Agreement (CRADA) under the authority of the Federal Technology Transfer Act of 1986 (FTTA), Public Law 99-502, codified as amended in scattered sections of title 15, United States Code (U.S.C.). The CRADA will delineate the collaboration for PTSD treatment intended to test new drugs to benefit Veterans.

DATES: This notice will remain open to accept inquiries and responses.

FOR FURTHER INFORMATION CONTACT: Interested parties should contact Theresa Gleason, Ph.D., Senior Program Manager, Clinical Science Research and Development Service at (202) 443-5697 or by e-mail at CLINreview@va.gov to provide an intention to participate. Please use the subject line: "DDI."

SUPPLEMENTARY INFORMATION: ORD has long supported a robust research portfolio of studies focused on understanding and treating PTSD, a disorder prevalent in Veterans. VA research has contributed extensively to advancing knowledge regarding the neurobiological underpinnings and leading advances in treatment research through clinical trials, especially in the area of psychotherapeutic approaches. Our program has the capability to conduct small/early to large/definitive multi-site clinical trials with the support of the VA Cooperative Studies Program. To identify and test new drug therapies for PTSD and to address the continuing need to treat Veterans with this disorder is of high interest to VA. This RFI is an invitation for responses from entities interested in participating in this DDI focused on new pharmacological treatments for PTSD.

Collaborations will be delineated via a CRADA under the authority of the FTTA at 15 U.S.C. 3710a. Under the FTTA, VA and the entity may exchange personnel, services, facilities, equipment, intellectual property, or other resources. No Federal funds may be provided to any third party collaborator, but the VA laboratory is authorized to accept funds. VA may grant to the collaborator party a license or an assignment to inventions made under the CRADA. We will select collaborators based on a mutually beneficial relationship that is fair and equitable and scientifically sound with the goal of advancing treatment for PTSD.

Responses to this RFI should include the following information:

- a. Company profile;
- b. Name, contact, and function of company representative; and

- c. Brief rationale for proposed compound as candidate to be tested as new treatment for PTSD. Please do not include proprietary, classified, confidential, or sensitive information in your response, but provide scientific basis for the use of the compound and the general status of testing completed to date in human subjects (if any).

We will evaluate DDI responses for interest. Selected potential collaborators may be invited to discussions to develop a CRADA and plan potential trials. Non-selected respondents will not receive additional feedback other than a non-selected notice. Special consideration will be given to small business firms and consortia involving small business firms. Preference will be given to businesses located in the United States which agree that products embodying inventions made under the CRADA will be manufactured substantially in the United States as provided for in 15 U.S.C. 3710a(c) (4).

This RFI does not obligate VA to enter into a CRADA with any respondent. VA reserves the right to establish a CRADA based on scientific analysis and capabilities found by way of this announcement or other searches if determined to be in the best interest of the government.

Approved: November 26, 2012

John R. Gingrich, Chief of Staff,
Department of Veterans Affairs.

